PATENT 674525-2002

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which are believed to place the application into condition for allowance.

L STATUS OF CLAIMS AND FORMAL MATTERS

Claims 2, 4, 5, 8, 9, 19, 20 and 25 are under consideration in this application. Claims 2, 5 and 25 are amended. Support for the amendments can be found throughout the specification and from the claims as originally filed. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art, and that these claims are and were in full compliance with the requirements of 35 U.S.C. § 112. Amendments to the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these changes are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTION UNDER 35 U.S.C. § 112, 2ND PARAGRAPH, IS OVERCOME

Claims 2, 4-9 and 20 were rejected under Section 112, second paragraph, as allegedly being indefinite. The Office Action questioned the term "upgrading" in claim 2. "Upgrading" has been replaced by "upregulating," obviating the rejection. Support for "upregulating" can be found on page 2, line 8, of the specification. Reconsideration and withdrawal of the indefiniteness rejection are requested.

III. THE REJECTION UNDER 35 U.S.C. § 112, 1ST PARAGRAPH, IS OVERCOME

Claims 5-7 and 25 were rejected under Section 112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

The Office Action states on page 3 that "IL-10 is the only composition used in the method of the instant claims demonstrated to be functional." Applicants make no admissions regarding the functionality of the active agents recited in claims 5-7, and maintain that a variety of species may be used in the methods of the invention. However, for the sake of expediency, claims 6 and 7 have been cancelled and claim 5 is amended to recite a composition comprising IL-10. Claim 25 has been similarly amended. Accordingly, reconsideration and withdrawal of the written description rejection are requested.

-5-

PATENT 674525-2002

IV. THE ART REJECTIONS UNDER 35 U.S.C. §§ 102 AND 103 ARE OVERCOME

Claims 2, 4-9, 19, 25 and 27 were rejected under Section 102(b) as allegedly being anticipated by Steinbrink et al. Claim 20 was rejected under Section 103(a) as allegedly being unpatentable over Steinbrink et al. in view of Scholz et al. The rejections are traversed.

Steinbrink et al. does not teach every element of the claimed invention. Claim 2 is directed to a method for producing a regulatory lymphocyte by incubating a mature APC with a composition capable of upregulating expression of Notch or a Notch ligand and with an allergen or antigen. On the other hand, Steinbrink et al. teaches a method for converting immature cells into tolerogenic APCs. (See the last line of the Abstract.) In fact, Steinbrink et al. teaches that "mature DC [dendritic cells] are completely resistant to the effects of IL-10." (See line 5 of the Abstract.) Thus, Steinbrink et al. does not disclose every element of the instant invention, but rather, presents teachings that are contrary to the current claims. In support of this assertion, Example 11, beginning on page 29 of the specification, demonstrates stimulation with IL-10 of mature dendritic cells. Therefore, Steinbrink et al. cannot anticipate the present claims.

Steinbrink et al. teaches away from the instant invention, and its combination with Scholz et al. does not remedy the deficiency of its teachings. Taken together, Steinbrink et al. and Scholz et al. do not teach the claimed method for producing a regulatory lymphocyte that promotes tolerance to one of the allergens or antigens recited in claim 20, because there is no teaching or suggestion in either reference of using a mature APC to produce the regulatory lymphocyte. Therefore, claim 20 cannot be obvious over the cited references.

Reconsideration and withdrawal of the art rejections are requested.

PATENT 674525-2002

CONCLUSION

In view of these remarks and amendments, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are requested.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

Thomas J. Kowalski Reg. No. 32,147

Arme-Marie C. Yvon, Ph.D. Reg. No. 52,390

(212) 588-0800